K103529

5.0 510(k) SUMMARY

JAN 2 1 2011

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	LIAISON® Anti-HAV, LIAISON® XL Analyzer
Common Names/Descriptions:	Hepatitis Anti-HAV, serological assay, Automated Chemiluminescent Immunoassay Analyzer
Regulation Number:	21 CFR 866.3310
Regulation Name:	Hepatitis A virus (HAV) serological assays
Regulatory Class:	Class II
Product Code:	LOL, JJF

PREDICATE DEVICES: LIAISON® Analyzer
Reference K082050

DEVICE DESCRIPTION:

INTENDED USE:
The LIAISON® Anti-HAV assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

This assay is not intended for screening blood or solid or soft tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing assay performance characteristics in these populations. Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

The LIAISON® XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for *in vitro* diagnostic analysis of CLIAs on human serum or plasma. The system menu includes infectious disease, bone and mineral, and endocrinology CLIAs. It is to be used only with FDA cleared chemiluminescence immunoassays that are marketed by DiaSorin for the LIAISON XL Analyzer.

The LIAISON® Control Anti-HAV (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Anti-HAV assay.

The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® and LIAISON® XL.

DESCRIPTION:

The method for qualitative determination of anti-HAV is a competitive sandwich chemiluminescence immunoassay (CLIA) based on neutralization. Antibodies to HAV (mouse monoclonal) are used for coating magnetic particles (solid phase) and are linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, anti-HAV present in calibrators, samples or controls binds to a fixed and limited amount of HAV, thus forming an HAV-anti-HAV immune complex. During the second incubation, the antibody conjugate and the solid-phase antibody compete with anti-HAV present in the specimen for HAV, that allows the conjugate to bind to the solid phase and thus form a "sandwich" of conjugate antibody-antigen-solid phase antibody. If all HAV added is sequestered in an HAV-anti-HAV immune complex during the first incubation, no sandwich is formed during the second incubation. After the second incubation, the unbound material is removed with a wash cycle.

Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is inversely indicative of anti-HAV present in calibrators, samples or controls

The LIAISON® XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay analyzer for *in vitro* diagnostic use.

COMPARISON TO PREDICATE DEVICE:

The following table compares the LIAISON® XL Analyzer to the LIAISON® Analyzer.

Summary of Device Similarities and Differences:

Feature	LIAISON® Analyzer	LIAISON® XL Analyzer
FDA K#	K032844/K082050	N/A
Intended Use	Automated chemiluminescent analyzer for clinical use	Same
Principles of operation	Chemiluminescence using magnetic particle solid phase and chemiluminescent tracer	Same
Optical System	High-sensitive, low-noise photomultiplier tube (PMT) operating as an ultra-fast photon counter. Pulses are amplified by a rapid electronic amplifier.	Same
	Circuit that suppresses PMT signal noise.	Same
	Linear measuring range = 300 – 650 nm	Same
	Light peak of chemiluminescence emitted at 450 nm	Same
Temperature Control: • Reaction Temperature • Reagent Storage Temperature	36°C±1°C 12-19°C	36°C±1°C 11-15°C
Dispense System	Automated pipetting of samples and reagents. Left pipetting unit used for samples; right pipetting unit used for reagents	same (sample pipetting: disposable tip)
	Precision syringes (sample and reagent)	same
	Sample Probe: - Liquid Level Detection (capacitive) - Clot Detection feature (software algorithm based on capacitive signal)	Sample Probe (disposable tip): - Liquid Level Detection and Clot Detection feature (pressure)
	N/A	Disposable tips: 6 trays of 96 tips each can be loaded on board. Monitored through software counter and presence sensor upon tip pick-up. Reloading allowed during run
	Reagent Probes: - Liquid Level Detection (capacitive), with software tracking of reagent level	Reagent Probes: - Liquid Level Detection (capacitive), with software tracking of reagent level - Optical Liquid Verification (real-time monitoring of liquid flow inside the probe)

Feature	LIAISON® Analyzer	LIAISON® XL Analyzer
Sample Handling	Capacity: Holds 12 sample racks, 12 places per rack	Capacity: Holds 10 sample racks, 12 places per rack
	Tube types: - primary tube - aliquot tube - pediatric	same
	Sample presence, sample type (calibrator, control, patient), tube size, and processing completion tracked by operating software and sample barcode	same
Reagent Handling	Capacity: 15 Reagent Integrals (RI)	Capacity: 25 Reagent Integrals (RI), plus 4 positions for Ancillary Reagents
	RI contains all reagents required for any given assay (up to 7 vials per RI, first always contains magnetic particles).	same
	Assay-specific processing and analysis parameters, calibration, lot number, expiration date, and usage (number of tests run) are controlled by operating software as communicated by barcode.	Assay-specific processing and analysis parameters, calibration, lot number, expiration date, and usage (number of tests run) are controlled by operating software as communicated by RF-Tag (RF-ID).
Additional Reagents	• Control Set (2-3 levels) • LIAISON Light Check (diagnostic tool only) • LIAISON Starter Kit (Starter Reagents 1 and 2) • LIAISON Wash/System Liquid • LIAISON Cleaning Kit	• Control Set (2-3 levels) • LIAISON Light Check (diagnostic tool only) • LIAISON Starter Kit (Starter Reagents 1 and 2) • LIAISON Wash/System Liquid (used as a wash liquid only – immunometric wash step) • LIAISON Cleaning Kit In addition: • Purified water is also required as System Liquid, as fluidic filler and to perform: - reagent needle cleaning - washer needle cleaning • A cleaning tank is available to host a cleaning liquid suitable for automated maintenance purpose
	Level sensing by capacitive rod	same
Reaction Modules	Capacity: 6 individual reaction compartments per Reaction Module	Single-cavity Cuvettes
	Storage capacity: maximum 120 strips stored in LIAISON stacker	Storage capacity: >600 Cuvettes

Feature	LIAISON® Analyzer	LIAISON® XL Analyzer
Reaction Modules (cont.)	Sensors detect presence of Reaction Modules, and loading and occupancy of stacker.	Inventory monitoring through software counter. Sensors detect actual presence of Cuvettes
	Reloading allowed during run	same
	Unloading automatic into waste bag	same
Test Processing	Random Access and Batch	same
	Continuous operation	same
	Sample scheduling optimized for throughput	same
Assay Protocols	1-Step assays: 1 incubation sequence / 1 wash sequence; average incubation time = 10 minutes	same
	2-Step assays: 2 incubation sequence / 1 or 2 wash sequence(s); average incubation time = 10 minutes	same
	Two-point calibration of assays	same
Human Interface	• Computer	same
	• Mouse and keyboard	Touch-screen On Screen Keyboard
	• Monitor – touch screen, color	same
	• Printer	Printer (optional)
	• Stationary barcode scanners for identification of samples and reagents	• Stationary barcode scanner for identification of samples • Stationary RF-Tag reader for identification of reagents (Reagent Integrals and Starter Reagents) • Handheld barcode scanner for identification of controls
	• Computer LIS Interface	same
Data Analysis	Automated data reduction	same
	Assay-specific Master Curve with 2-point recalibration	same
	Assay-specific data reduction	same
QC Software	Stored lot-specific control results	same
	Lot-specific Levey-Jennings plotting	same
	Trend identification	same
	Statistical analyses	same
Specimens	Serum or plasma	same
	Sampling from primary, aliquot, or pediatric tubes	same
Disposables	• Reagent Integrals	same
	• Light Check (diagnostic tool)	same
	• Starter Kit	same
	• Wash/System Liquid	same
	• Reaction Modules	• Cuvettes
	N/A	• Disposable Tips
	• Waste Bag	same (dedicated)
	• Cleaning Kit	same (dedicated)

Feature	LIAISON® Analyzer	LIAISON® XL Analyzer
Hardware Improvements	LIAISON® Analyzer	LIAISON® Analyzer, with enhancements as follows:
		• floor-standing, integrated design • improved average throughput, • Improved data exchange for Reagent Integrals, Ancillary Reagents, Starter Reagents via RF-ID technology • Disposable tip for sample pipetting • Continuous loading of all liquid and solid resources or waste • Increased liquid/reagent capacity • Increased efficiency of washer needle cleaning • Automated Maintenance tasks • On-line help: User Manual and Quick Guide directly accessible on screen

CONCLUSION:

The material submitted in this premarket notification is complete and supports the substantial equivalence of the LIAISON® XL Analyzer to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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JAN 21 2011

Re: K103529
Trade/Device Name: LIAISON Anti-HAV, LIAISON XL Analyzer
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL, JJF
Dated: November 30, 2010
Received: December 1, 2010

Dear Ms. Meyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

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Prescription Use __X__ (21 CFR Part 801 Subpart D)

And/Or Over the Counter Use_____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103529